

**Notice of Allowability**

Application No.

10/796,441

Applicant(s)

RADOMSKY, MICHAEL

Examiner

Michael C. Henry

Art Unit

1623

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 11/14/05.
2. ☒ The allowed claim(s) is/are 17-22. These claims are renumbered 1-6, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|   | 9. <input type="checkbox"/> Other _____   |



### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 01/28/03.

The amendment filed 11/14/05 affects the application, 10/796,441 as follows:

1. Claims 1-16 have been canceled. This leaves claims 17-22. Upon further consideration the examiner has determined that applicant's amendments have overcome the rejection of the final office action and has placed the application in condition for allowance. Furthermore applicant's timely filed terminal disclaimer dated 03/03/05 is sufficient to overcome the double patenting rejection of the prior office action.

### ***REASONS FOR ALLOWANCE***

The following is an examiner's statement of reasons for allowance: The examiner has found claims 17-22 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to a method of treating diseased, injured or abnormal bone at a site of desired bone growth comprising the step of applying to said site a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients to maintain biological activity of said factor, said composition being sufficient to enhance bone growth rate and magnitude and having a viscosity and biodegradability sufficient to persist at said site for a period of time sufficient to enhance said bone growth rate and magnitude." The very relevant prior art documents (WO 95/24211 and US 5,432,167) to this invention disclose a method of bone healing with bFGF in BSA in PBS and a method of treating bone fractures (injured bone) with hyaluronic acid. However, neither documents teach or suggest treating bone injuries with a combination of hyaluronic acid and a



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growth factor. Moreover, applicant's composition which comprises a mixture of hyaluronic acid, a growth factor and excipients produces a synergistic effect of treating bone growth.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

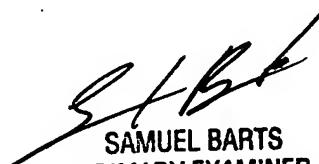
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

November 22, 2005.

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 180